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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,854	04/05/2001	Vassilis I. Zannis	07180/004003	6635

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/02/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/827,854

Applicant(s)

ZANNIS ET AL.

Examiner

Quang Nguyen, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-49 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

- I. Claims 1-14, 30-47 and 49, drawn to a nucleic acid encoding a polypeptide of between 150 and 299 amino acids that has an amino acid sequence at least 50% identical to that of the corresponding region of amino acids 1 to 299 of a mature, native human apoE polypeptide; a recombinant DNA molecule comprising a nucleic acid operatively linked to a promoter, said nucleic acid encoding a polypeptide of between 150 and 299 amino acids that has an amino acid sequence at least 80% identical to that of the corresponding region of amino acids 1 to 299 of a mature, native, human apoE polypeptide; and a method of lowering cholesterol, delaying the onset of atherosclerosis or regressing atherosclerosis in a mammal without inducing hypertriglyceridemia using the same recombinant DNA molecule, classified in class 514, subclass 44; class 536, subclass 23.5 . It is noted that as written in claim 35, it is unclear how the vector of the presently claimed invention is administered by bone marrow transplantation into a mammal. Should it be clarified that bone

marrow cells transfected with the vector of the instant invention being administered into a mammal for lowering cholesterol, delaying the onset of atherosclerosis or regressing atherosclerosis, further group restriction will be made because the nature of this invention is a genetically modified cell-based gene therapy and not *in vivo* gene therapy, classified in class 424, subclass 93.21, that has different technical considerations for achieving the results contemplated by Applicants.

- II. Claims 15-29 and 48, drawn to a polypeptide of between 150 and 299 amino acids, said polypeptide having an amino acid sequence at least 50% identical to the corresponding region of amino acids 1-299 of a mature, native, human apoE; a pharmaceutical composition comprising a polypeptide admixed with a pharmaceutically acceptable carrier substance, wherein said polypeptide consisting of between 150 and 299 amino acids and having an amino acid sequence at least 80% identical to the corresponding region of amino acids 1-299 of a mature, native human apoE; and a method of lowering cholesterol, delaying the onset of atherosclerosis or treating atherosclerosis in a mammal without inducing hypertriglyceridemia using the same pharmaceutical composition, classified in class 514, subclass 2; class 530, subclasses 350, 359.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II differ one from the other because the nucleic acid molecule or a recombinant DNA molecule of Group I is composed of nucleotides

whereas the polypeptide of Group II is made of amino acid residues. Additionally, the method of Group I involves a different starting material (a nucleic acid molecule), and it belongs to a gene therapy art that requires different technical consideration for attaining the desired end-results, whereas the method of Group II belongs to a protein therapy method that requires different technical considerations for achieving the same end-results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of both inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect Group I, claims 1-14, 30-47 and 49 are generic to a plurality of disclosed patentably distinct species comprising:

(a) SEQ ID NO: 14; (b) SEQ ID NO: 15; (c) SEQ ID NO: 16; (d) SEQ ID NO: 17; SEQ ID NO: 18; and (e) SEQ ID NO: 19.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, Claims 30, 33-34, 36, 43-44, 46-47 are generic to a plurality of disclosed patentably distinct species of administered recombinant viral vector comprising:

(a) adenoviral vector, (b) adeno-associated viral vector, (c) lentiviral vector, (d) herpes viral vector, (e) retroviral vector, and (f) baculoviral vector.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect Group II, claims 15-29 and 48 are generic to a plurality of disclosed patentably distinct species comprising:

(a) SEQ ID NO: 1; (b) SEQ ID NO: 2; (c) SEQ ID NO: 3; (d) SEQ ID NO: 4; SEQ ID NO: 5; and (e) SEQ ID NO: 6.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600